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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,375	02/28/2002	Cecil W. Forsberg	6580-270	9974
1059	7590	01/12/2006	EXAMINER	
BERESKIN AND PARR			BERTOGLIO, VALARIE E	
40 KING STREET WEST			ART UNIT	PAPER NUMBER
BOX 401			1632	
TORONTO, ON M5H 3Y2				
CANADA				
DATE MAILED: 01/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/926,375	FORSBERG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 October 2005.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12,17,19,22-24,27-31 and 33-57 is/are pending in the application.  
 4a) Of the above claim(s) 36-57 is/are withdrawn from consideration.  
 5) Claim(s) 1-12,30-31 and 33-35 is/are allowed.  
 6) Claim(s) 17,19,22-24, 27,29 is/are rejected.  
 7) Claim(s) 28 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 10/23/2001 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

Applicant's reply filed 10/11/2005 has been received. Claims 1-12, 17, 19, 23, 29 and 30 have been amended. Claims 13-16, 18, 20, 21, 25, 26 and 32 are cancelled. Claims 36-57 are withdrawn. Claims 1-12, 17, 19, 22-24, 27-31 and 33-57 are pending and claims 1-12, 17, 19, 22-24, 27-31 and 33-35 are under consideration in the instant office action.

### *Claim Objections*

The objection to claims 1, 13 and 19 is withdrawn in light of Applicants' amendment to the claims.

Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### *Claim Rejections - 35 USC § 112-1<sup>st</sup> paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 19, 22-24, 27 and 29 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic non-human mammal whose genome comprises a transgene comprising a gene encoding a phytase operably linked to a mammalian salivary gland promoter wherein the mammal is a pig, goat, sheep, cow, or horse, wherein the phytase is expressed in the salivary gland and secreted into the saliva of the mammal

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does not reasonably provide enablement for said transgenic mammal expressing and/or secreting phytase in any other region of the gastrointestinal tract. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is maintained in part as set forth at pages 3-5 of the previous office action dated 08/12/2005 as discussed below.

Applicant's arguments have been thoroughly considered and are partially persuasive. Applicant's amendments to the claims fail to overcome the lack of support in the specification at the time the application was filed for expression of phytase anywhere in the gastrointestinal tract other than the salivary gland, which now applies to amended claims 17,19,22-24, 27,29. Claims 19,22-24,27 and 29 were not previously subject to this particular aspect of the rejection in the previous office action dated 08/12/2005 because claim 19 contained the limitation "salivary-specific" and the salivary gland is an organ in the gastrointestinal tract. Therefore, the claim was considered supported by the specification (see page 5, paragraph 2). It is noted that the claims were rejected under 35 USC 112, 2<sup>nd</sup> paragraph for the use of this terminology, which was subsequently amended. Currently, the claims encompass use of any salivary regulatory sequence, wherein expression and secretion occurs in other regions of the gastrointestinal tract other than the salivary gland, and is required for claim 17. The encompassed scope of expression is not supported by the instant specification as filed because the salivary regulatory sequences taught in the specification were not demonstrated to drive gene expression in any tissue other than the salivary gland and no other regulatory sequences were disclosed. Claim 28 is excluded from this rejection because the claims sufficiently narrow the promoter sequences to those specifically described in the specification that lead to salivary expression, which is a gastrointestinal organ.

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and do not encompass any other salivary promoter sequences that may or may not have additional expression domains. It is noted that claim 28 does not require additional expression domains as is the case for claim 17.

Applicant argues that post-filing evidence supports the claimed expression outside the salivary gland using the described salivary regulatory sequences. However, the specification, at the time of filing was not enabling for expression anywhere outside the salivary gland. Applicant appears to aim to not necessarily exclude the expression outside the salivary gland that was determined to be present after the filing of the instant application (see page 10, paragraph 3 of Applicant's Remarks). In response, the Examiner has not required a limitation to the claims that there be no expression outside the salivary gland. Rather, the claim should not contain limitations that include expression in organs not supported by the specification. Therefore, Applicant should amend the claims to remove reference to expression and secretion in the gastrointestinal tract.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 19,22,24,27-29 under 35 U.S.C. 112, second paragraph as set forth at pages 7-8 of the previous office action dated 08/12/2005 is withdrawn.

The following new rejection is necessitated by the amendments to the claims.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 23 recites the limitation "said animal" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 30,31 and 33-35 under 35 U.S.C. 103(a) is withdrawn in light of Applicant's arguments regarding the expectation of success in expressing phytase in the digestive system of large mammals and the limitation of the claims to such large species.

***Allowable Subject Matter***

Claim 1-12,30-31 and 33-35 are allowed.

Claim 28 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

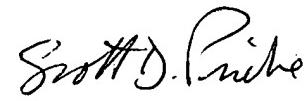
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio  
Examiner  
Art Unit 1632

  
SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER